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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,501	12/13/2001	Charles F. Streckfus	4856-CIP	8069
22922	7590	10/21/2003		
REINHART BOERNER VAN DEUREN S.C. ATTN: LINDA GABRIEL, DOCKET COORDINATOR 1000 NORTH WATER STREET SUITE 2100 MILWAUKEE, WI 53202			EXAMINER HOLLERAN, ANNE L	
			ART UNIT	PAPER NUMBER
			1642	16
			DATE MAILED: 10/21/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,501

Applicant(s)

STRECKFUS ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-14 is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed April 30, 2003 is acknowledged. Claims 15-20 were canceled.
2. The terminal disclaimer filed on April 30, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the expiration date of patent resulting from U.S. application 09/962,477, allowed, has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. Claims 1-14 are pending and examined on the merits.

Claim Rejections Withdrawn:

4. The rejection of claims 15-20 under 35 U.S.C. 101 as claiming the same invention as that of claims 12-17 of prior U.S. Patent No. 6,294,349 is withdrawn in view of the amendment canceling claims 15-20.
5. The rejection of claims 1-6, 9-11, and 13-20 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-29 of copending Application No. 09/962,477 is withdrawn in view of the terminal disclaimer.

New Grounds of Rejection:

6. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to describe the generic “biomarker reference panel that includes biomarker constituents”.

The specification describes a biomarker reference panel that consists of constituents that are cancer antigen 15-3, tumor suppressor oncogene protein 53 and oncogene c-erB-2. The specification fails to describe other biomarker reference panels and what the constituents of these panels are, and also fails to show how these panels could be used to make a differential diagnosis between malignant tumor, benign tumor or control population. Furthermore, the reference panel that is described is not representative of any reference panel that may be within the scope of these claims. Additionally, the presence of claim 6, indicating that each constituent is associated with a concentration value, leads one to ask what else each constituent may be associated with. The specification only describes the case where concentration levels between measured and a reference concentration are compared, not any other comparison. Because the description of a method is inadequate when the description of the products or compositions that will be used in the claimed methods is inadequate, in the instant case, the specification fails to describe the claimed methods.

Conclusion

Claims 1-9 are rejected. Claims 10-14 are allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran

Patent Examiner

October 6, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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